

K113156

NOV 15 2011

510(K) Summary

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official: Scott E. Paulson
Sr. Regulatory Affairs Specialist
E-mail: Scott.Paulson@sonosite.com
Telephone: (425) 951-6926
Facsimile: (425) 491-8356
Date prepared: October 4, 2011

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite Edge™ Ultrasound System (*subject to change*)

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Picture Archiving and Communications System	892.2050	LLZ

3) Identification of the predicate or legally marketed device:

SonoSite Maxx Series Ultrasound System K071134 / K082098

4) Device Description:

The SonoSite Edge Ultrasound System is a portable laptop style, full featured, general purpose, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. Edge is a custom fabricated digital electronic design that readily lends itself to be configured for specific ultrasound imaging applications through different system feature selections. Edge can operate on either battery or AC power.

5) **Intended Use:**

The intended uses of the SonoSite Edge Ultrasound System as defined by FDA guidance documents, are:

Ophthalmic	Adult Cephalic
Fetal - OB/GYN	Trans-rectal
Abdominal	Trans-vaginal
Intra-operative (Abdominal organs and vascular)	Musculo-skel. (Conventional)
Intra-operative (Neuro.)	Musculo-skel. (Superficial)
Laparoscopic	Cardiac Adult
Pediatric	Cardiac Pediatric
Small Organ (breast, thyroid, testicles, prostate)	Trans-esophageal (card.)
Neonatal Cephalic	Peripheral vessel

6) **Technological Characteristics:**

SonoSite Edge and Maxx Series Ultrasound Systems are both Track 3 devices that employ the same fundamental scientific technology.

7) **Determination of Substantial Equivalence:**

Summary of Non-Clinical Tests:

The SonoSite Edge Ultrasound System has been evaluated for electrical, thermal, mechanical and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated, and the device has been found to conform to all applicable mandatory medical device safety standards. The Edge system also complies with voluntary standards which are detailed in Table 1.1-1 and 1.1-2 of this premarket submission. Assurance of quality was established by employing the following elements of product development: System and Software Verification, Hardware Verification, Safety Compliance Verification, Clinical Validation, Human Factors Validation. All patient contact materials are biocompatible. Reports for these product development elements are referenced in Attachment 6.

Summary of Clinical Tests:

The SonoSite Edge Ultrasound System and transducers did not require clinical studies to support the determination of substantial equivalence.

The SonoSite Maxx Series Ultrasound System is designed to comply with the following standards.

FDA Consensus Standards

Reference No.	Title
AAMI/ANSI/ISO 10993-1	ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing
AAMI/ANSI/ISO 10993-5	ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
AAMI/ANSI/ISO 10993-12	ISO 10993-12:2007, Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 15 2011

SonoSite, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K113156
Trade/Device Name: SonoSite Edge TM Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, and LLZ
Dated: October 25, 2011
Received: October 26, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite Edge TM Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>C8x/8-5 MHz</u>	<u>HFL38x/13-6 MHz</u>	<u>L38x/10-5 MHz</u>
<u>C11x/8-5 MHz</u>	<u>HFL50x/15-6 MHz</u>	<u>P10x/8-4 MHz</u>
<u>D2x/2 MHz Dual Element</u>	<u>ICTx/8-5 MHz</u>	<u>P21x/5-1 MHz</u>
<u>Circular Array</u>	<u>L25x/13-6 MHz</u>	<u>SLAx/13-6 MHz</u>
<u>C60x/5-2 MHz</u>	<u>L38xi/10-5 MHz</u>	<u>TEEx/8-3 MHz</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

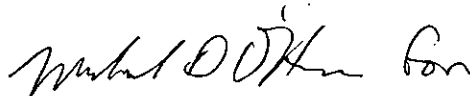
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mary S. Pastel", followed by a small "for" in cursive.

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Form

510(k) Number (if known): TBD **K113156**

Device Name: SonoSite Edge™ Ultrasound System

Indications for Use:

The SonoSite Edge Ultrasound System is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Ophthalmic, Fetal - OB/GYN, Abdominal, Intraoperative (abdominal organs and vascular), Intra-operative (Neuro.), Pediatric, Small Organ (breast, thyroid, testicle, prostate), Neonatal Cephalic, Adult Cephalic, Trans-Rectal, Trans-Vaginal, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (cardiac), Peripheral Vessel.

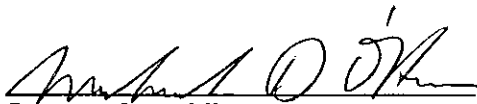
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113156

Table 1.3-1 Diagnostic Ultrasound Indications for Use Form – SonoSite Edge™ Ultrasound System

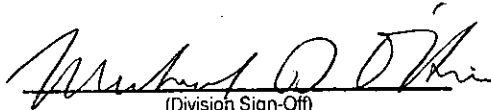
System:	SonoSite Edge™ Ultrasound System						
Transducer:	N/A						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Adult Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Trans-rectal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Trans-vaginal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), color TDI, and imaging for guidance of biopsy. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Includes imaging of spinal cord to provide guidance for central nerve block procedures. Includes picture archiving, communications and storage functionality. M-Mode includes color M-Mode.

Prescription Use (Per 21 CFR 801.109)


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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113156

Table 1.3-2 Diagnostic Ultrasound Indications for Use Form – C8x/8-5 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	C8x/8-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134 and K082098.

Prescription Use (Per 21 CFR 801.109)

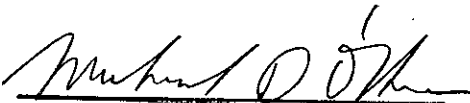

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 510K K113150

Table 1.3-3 Diagnostic Ultrasound Indications for Use Form – C11x/8-5 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	C11x/8-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)



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 510K K113156

Table 1.3-4 Diagnostic Ultrasound Indications for Use Form – D2x/2 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	D2x/2 MHz Dual Element Circular Array						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult				P			
Cardiac Pediatric				P			
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)



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 510K K113156

Table 1.3-5 Diagnostic Ultrasound Indications for Use Form – C60x/5-2 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	C60x/5-2 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

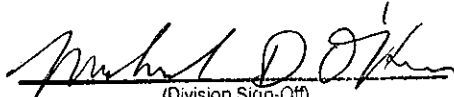

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 510K K11315C

Table 1.3-6 Diagnostic Ultrasound Indications for Use Form – HFL38x/13-6 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	HFL38x/13-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBE compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

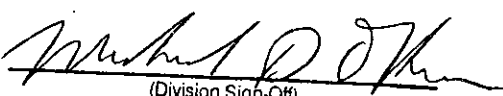

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510K K113156

Table 1.3-7 Diagnostic Ultrasound Indications for Use Form – HFL50x/15-6 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	HFL50x/15-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

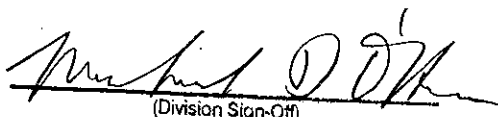

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 510K K113156

Table 1.3- 8 Diagnostic Ultrasound Indications for Use Form – ICTx/8-5 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	ICTx/8-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

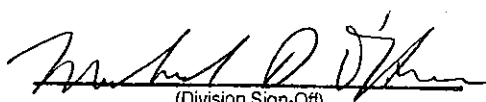

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 510K K113156

Table 1.3- 9 Diagnostic Ultrasound Indications for Use Form – L25x/13-6 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	L25x/13-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P			P	B+M; B+CD	Note 1
Fetal							
Abdominal	P	P			P	B+M; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P			P	B+M; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P			P	B+M; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P			P	B+M; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134 and K082098.

Prescription Use (Per 21 CFR 801.109)



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Table 1.3- 10 Diagnostic Ultrasound Indications for Use Form - L38xi/10-5 Transducer

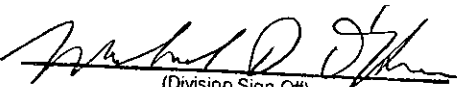
System:	SonoSite Edge™ Ultrasound System						
Transducer:	L38xi/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

Prescription Use (Per 21 CFR 801.109)


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Table 1.3- 11 Diagnostic Ultrasound Indications for Use Form - L38x/10-5 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	L38x/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)



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Table 1.3- 12 Diagnostic Ultrasound Indications for Use Form – P10x/8-4 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	P10x/8-4 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Fetal	P	P	P		P	B+M; B+PWD B+CD	Note 1
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Neonatal Cephalic	P	P	P		P	B+M; B+PWD B+CD	Note 1
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), color TDI, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)



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Table 1.3- 13 Diagnostic Ultrasound Indications for Use Form – P21x/5-1 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	P21x/5-1 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Fetal	P	P	P		P	B+M; B+PWD B+CD	Note 1
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Neonatal Cephalic	P	P	P		P	B+M; B+PWD B+CD	Note 1
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), color TDI, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)



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Table 1.3- 14 Diagnostic Ultrasound Indications for Use Form – SLAx/13-6 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	SLAx/13-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134 and K082098.

Prescription Use (Per 21 CFR 801.109)



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Table 1.3- 15 Diagnostic Ultrasound Indications for Use Form – TEEEx/8-3 Transducer

System:	SonoSite Edge™ Ultrasound System						
Transducer:	TEEx/8-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Other (spec.)							
Peripheral vessel							
Other (spec.)							

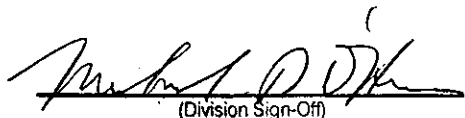
N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBc compound imaging, tissue Doppler imaging (TDI), color TDI, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)


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